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EXAMINER

WEINSTEIN, STEVEN L

ART UNIT

PAPER NUMBER

1761

DATE MAILED: 10/27/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/887028

Applicant(s)

SNAPIRA

Examiner

S. WEINSTEIN

Group Art Unit

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— The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address —

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- ☒ Responsive to communication(s) filed on 7/24/03
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-14 is/are pending in the application.
- Of the above claim(s) 8-14 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-7 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement

## Application Papers

- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
- ☐ All ☐ Some\* ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
- ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_ ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other \_\_\_\_\_

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Applicant's election without traverse, filed 7/24/03, paper no.6, to the election of species mailed 7/8/03, paper no.5 is noted. Applicant elected species II and listed claims 1-5 and 7 as readable thereon. In view of the art discovered by the examiner during the course of a search, the election of species requirement is hereby withdrawn and an action on claims 1-7 follows.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 USC112, first paragraph. As disclosed, the object of the invention appears to be to feed an infant milk that simulates the fat content that the infant would receive during a breast-feeding which is an initial milk or fore-milk, which has a lower fat content than a hind-milk that occurs later during the same breast-feeding session. The disclosed process is to give the infant a portion of low fat milk, which is followed by a portion of a higher fat milk at the same feeding. It does not appear that the specification supports general feeding steps which do not follow the sequence of low then high fat content and which do not even recite that the two compositions are given to the infant at the same feeding. It is also noted that there appears to be an inconsistency in the specification which appears to define "fore-milk equivalent" and "hind-milk equivalent" as milk substitute which are "similar" or "compatible" at least in their fat content "and/or" other ingredients... However, since it appears that the major defining difference between fore and hind milk is their fat

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content, then is applicant disclosing that the two milk substitutes can have the same fat content? If so, could they then be truly termed fore and hind-milk?

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2,3 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Woolridge et al (Lancet, vol. ii, 8207, p.1292-1294, 1980).

In regard to claim 1, Woolridge et al discloses feeding an infant low fat milk and then high fat milk "simulating the change in milk composition during breast feeding". Thus, Woolridge clearly anticipates claim 1 since Woolridge et al meets the definition of a foremilk and hind-milk equivalent (i.e. One that is similar or compatible at least in their fat content"). The milk is also a substitute since, at the minimum, it has been modified. In regard to claim 3, as noted above, Woolridge et al discloses that the two milk portions are fed to the child one after the other and in regard to claim 6, Woolridge et al discloses using two bottles, In regard to claim 2, since the objective of Woolridge et al is to produce a milk simulating the change in milk composition during breast feeding, then it is considered that Woolridge et al would anticipate the recognized fat content for foremilk that is recited. Woolridge et al also teaches a 50-50% volume of fore and hind milk with claim3 reciting 30-60%.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woolridge et al in view of Stehlin (FDA consumer V.30, 6/96, p.17-20) Kavanagh (Food Ingredients. Europe, 11/95, 123-126), Uhle (Mil Chwissen Schaft, 29 (5), 265-274, 1974) and Zubkova et al (xix Int'l Dairy Congress, Vol. 1E, p639, 1974)

In regard to claims 4 and 5, the claims differ from Woolridge et al in their percentage of foremilk. The examiner will attempt to obtain the complete article. It is not clear, from Woolridge et al and there appears to be some confusion, as to whether the milk that has its fat content altered is human breast milk or cows milk or some formula. In any case, Woolridge et al teaches 50% foremilk, and to modify Woolridge et al and vary the percentages of fore to hind milk is seen to have been an obvious routine determination. Stehlin, Kavanagh, Uhle and Zubkova are relied on to teach the art is replete with teachings to simulate, copy, reproduce or imitate, human breast milk.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Woolridge et al in view of Simmons et al (5, 611776)

Claim 7 differs from Woolridge et al in how the two milk compositions with different fat compositions is delivered to the child. Woolridge et al discloses two bottles where in claim 7 recites a bottle with two compartments. As evidenced by Vinciguerra, it is well established to feed a child two different liquids by employing a two-compartmented bottle and to modify Woolridge et al and substitute one conventional

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delivery system for another conventional delivery system for its art recognized and applicants intended function would have been obvious.

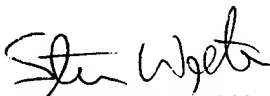
Any inquiry concerning this communication from the examiner should be directed to Steven Weinstein whose telephone number is 703-308-0650. The examiner can generally be reached on Monday-Friday 7:00am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on 703-308-3959. The fax phone numbers for the organization where this application is assigned is (703) 872-9310 for regular communications and (703) 872-9311 for after final communications.

Any inquiry of a general nature or relating to the status of this should be directed to the receptionist whose telephone number is 703-308-0661.

S. Weinstein/lap  
October 14, 2003

Corrected 10/21/03

  
STEVE WEINSTEIN  
PRIMARY EXAMINER 1761  
10/24/03